

TAB E

DRAFT 2/10/98

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CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1700

Proposed Rule: Requirements for Child-Resistant Packaging;
Minoxidil Preparations with More Than 14 mg of Minoxidil
Per Package

AGENCY : Consumer Product Safety Commission.

ACTION: Proposed rule.

SUMMARY: The Commission is proposing a rule to require child-resistant ("CR") packaging for minoxidil preparations containing more than 14 mg of minoxidil in a single package. The Commission has preliminarily determined that child-resistant packaging is necessary to protect children under 5 years of age from serious personal injury and serious illness resulting from handling or ingesting a toxic amount of minoxidil. The Commission takes this action under the authority of the Poison Prevention Packaging Act of 1970.

DATES: Comments on the proposal should be submitted no later than _____ [insert date that is 75 days after publication in the FEDERAL REGISTER].

ADDRESSES: Comments should be mailed to the Office of the Secretary, Consumer Product Safety Commission, Washington, D.C. 20207, or delivered to the Office of the Secretary, Consumer Product Safety Commission, Room 502, 4330 East-West Highway, Bethesda, Maryland 20814-4408, telephone (301)504-0800. Comments

may also be filed by telefacsimile to (301) 504-0127 or by email to cpsc-os@cpsc.gov.

FOR FURTHER INFORMATION CONTACT: Suzanne Barone, Ph.D., Division of Health Sciences, Directorate for Epidemiology and Health Sciences, Consumer Product Safety Commission, Washington, D.C. 20207; telephone (301)504-0477 ext. 1196.

SUPPLEMENTARY INFORMATION::

A. Background

1. Relevant Statutory and Regulatory Provisions

The Poison Prevention Packaging Act of 1970 ("PPPA"), 15 U.S.C. 1471-1476, authorizes the Commission to establish standards for the "special packaging" of any household substance if (1) the degree or nature of the hazard to children in the availability of such substance, by reason of its packaging, is such that special packaging is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substance and (2) the special packaging is technically feasible, practicable, and appropriate for such substance.

Special packaging, also referred to as "child-resistant (CR) packaging," is (1) designed or constructed to be significantly difficult for children under 5 years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time and (2) not difficult for "normal adults" to use properly. 15 U.S.C. 1471(4). Household substances for which the Commission may require CR packaging include (among other

categories) foods, drugs, or cosmetics as these terms are defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321). 15 U.S.C. 1471(2)(B). The Commission has performance requirements for special packaging. 16 CFR 1700.15, 1700.20. Under these requirements, most special packaging must be child-resistant (85 percent of a panel of 200 children cannot open it without a demonstration and 80 percent cannot open it with a demonstration) and senior-friendly ("SF") (90 percent of a panel of 100 adults ages 50 to 70 must be able to open the packaging).

Section 4(a) of the PPPA, 15 U.S.C. 1473(a), allows the manufacturer or packer to package a nonprescription product subject to special packaging standards in one size of non-CR packaging only if the manufacturer (or packer) also supplies the substance in CR packages of a popular size, and the non-CR packages bear conspicuous labeling stating: "This package for households without young children." 15 U.S.C. 1473(a), 16 CFR 1700.5.

2. Minoxidil

Topical minoxidil is a liquid medication that is applied to the scalp to stimulate hair regrowth for individuals with a common form of genetic hair loss (androgenetic alopecia). In February 1996, the Food and Drug Administration ("FDA") approved the sale of topical minoxidil as an over-the-counter ("OTC") drug available without a prescription. There is also a tablet form of minoxidil for treatment of severe hypertension that is available only by prescription. Like most oral prescription drugs, the

prescription form of minoxidil must be in special packaging. 16 CFR 1700.14(a) (10). However, special packaging is not required for topical drugs unless the Commission takes specific action to require it.

Topical minoxidil first became available by prescription in 1988. The OTC preparation is currently marketed as a two percent solution in 60 percent alcohol, propylene glycol, and water. The package instructions direct the user to apply one milliliter (20 milligrams of minoxidil) to the scalp twice a day. This application generally must continue for four months for there to be any noticeable hair growth. Continuous application is necessary to maintain the newly grown hair. The most prevalent package size contains 60 milliliters of the preparation (1200 milligrams of minoxidil) which is a 30-day supply if used as directed.(2)¹ On November 14, 1997, The FDA approved for OTC use a 5% minoxidil solution for men. The package size is also 60 milliliters, and the recommended dosage is one milliliter (50 milligrams of minoxidil) applied twice a day. The total contents of the package is 3000 milligrams.

The Commission is aware of ten manufacturers that have FDA's approval to market the OTC two percent minoxidil solution. In addition, the Commission knows of six other companies -- probably repackagers or relabelers -- that sell the OTC minoxidil formulation. The year after FDA approved OTC status for topical

¹ Number in parentheses refer to documents listed at the end of this notice.

minoxidil preparations, retail sales of topical minoxidil were about \$200 million (approximately 8 million packages).(3)

Topical minoxidil formulations are generally packaged either for men or for women. Although the formulations are the same, the packaging and instructions are different. All the bottles the Commission is aware of are secured with child resistant ("CR"), senior friendly ("SF") continuous threaded closures. In addition to the primary closure, the packages the Commission staff examined contain one or more applicators that are intended to replace the primary closure once the product has been used for the first time.

The Commission staff examined nine topical minoxidil packages for men. These packages contained dropper applicators. In six of these, the droppers were CR/SF, the other three droppers were non-CR. Four of the packages for men also contained a metered finger mechanical sprayer applicator (hereafter referred to as a "finger sprayer") in addition to the dropper applicator. The finger sprayer releases the solution in a mist which the package insert claims may be more useful than a dropper for broader areas of hair loss. None of the finger sprayers are CR.(4)

Hair loss for women occurs as a thinning of the hair over a broad area on the top of the scalp rather than at the vertex. All four of the topical minoxidil packages for women that the staff examined contained the metered finger mechanical sprayer applicator. Two products for women included a CR/SF dropper in

addition to the finger sprayer. Three packages for women included an extender attachment to fit onto the finger sprayer applicator allowing the solution to be applied closer to the scalp than the pump spray alone would manage. Neither the finger sprayers nor the extenders in the packages intended for women were CR.(4)

3. CR Packaging for Applicators

Because the topical minoxidil formulations are packaged with applicators intended to replace the primary closure of the product after its first use, the question arises whether the applicators themselves must be CR if the Commission requires CR packaging for the product.' The Commission has not previously addressed this issue.

Under the PPPA, a "package" is the "immediate container" that holds a substance when it is located in the household. Specifically, the term "package" is defined as:

the immediate container or wrapping in which any household substance is contained for consumption, use, or storage by individuals in or about the household.

15 U.S.C. 1471(3). Clearly, the focus of this definition is on how the product is packaged in the home where it is "contained for consumption, use or **storage**" rather than its packaging in the store. This is fully consistent with the purpose of the statute, to reduce child poisonings from available household substances.

The exclusions from the definition of "package" also indicate that Congress was concerned with the package as

maintained in the home. Congress excluded containers used only to transport the product. Thus, "package" does not include:

(A) any shipping container or wrapping used solely for the transportation of any household substance in bulk or in quantity to manufacturers, packers, or processors, or to wholesale or retail distributors thereof, or

(B) any shipping container or outer wrapping used by retailers to ship or deliver any household substance to consumers unless it is the only such container or wrapping.

Id.

The legislative history of the statute also supports the view that the "package" includes applicators intended to be used as closures in the home. The Senate Commerce Committee Report notes: "The term 'package' was defined here to [sic] in order to make explicit that special packaging refers to that package in which the substance is kept in or around the house." S. Rep. 845, 91st Cong., 2d Sess. 9 (1970).

Thus, the Commission believes that when an applicator is packaged with a product that requires CR packaging and the applicator is intended to replace the original closure of the packaging, that applicator must also be CR. This does not mean that every applicator packaged with a substance requiring CR packaging must itself be CR. It is permissible for an applicator, such as a dropper, to be packaged with a product so long as the applicator cannot be used to replace the original closure.

Early in the Commission's administration of the PPPA, the staff recognized the potential problem posed by applicators used to replace original closures. Accordingly, the staff advised that dropper bottles are not excepted from the PPPA's requirements. In 1974, the staff advised the Arizona State Board of Pharmacy that if a manufacturer of prescription drugs dispensed with droppers could not provide CR closures incorporating the dropper, the drug could be packaged with a conventional CR closure accompanied by a separate non-closing dropper. (See letter to Alfred J. Duncan, Executive Secretary of the Arizona State Board of Pharmacy from Robert Poth, April 11, 1974.) This position was reiterated in an internal staff memorandum stating "when a prescription drug is packaged in a dropper bottle, it is the dropper bottle that is the 'package' and any packaging exterior to this cannot be considered the 'package.' " The memo continues: "[U]ntil special packaging is available for the dropper unit itself, manufacturers should place the drug in a specially packaged bottle, with a separate dropper provided for proper administration of the drug. However, in our view, the separately provided dropper should not contain a cap, since the consumer would be apt to use the dropper and noncomplying cap permanently, and discard the special cap."

(Memo from Poth and Lemberg, June 12, 1974.) The staff discussed this position with staff at the FDA a few months later. The FDA staff agreed with the Commission staff's approach. (Memorandum

of meeting between FDA and CPSC representatives, October 15, 1974.)

Because the Commission has not previously addressed this question explicitly in a regulation, the proposed rule that the Commission issues today expressly states that applicators packaged with topical minoxidil that are intended to replace the original closures would be required to be CR and SF. The Commission recognizes that its other rules, such as the rule covering oral prescription drugs, do not contain such a provision. When previous special packaging rules were issued, few packages contained applicators intended to be used as closures. Thus, previous rules did not expressly state that such applicator closures are "packages" under the PPPA. In order to clarify the issue, the Commission proposes to include such a statement in the proposed rule for minoxidil. The lack of such a statement in previous PPPA rules is not to be construed to mean applicator closures are exempt from special packaging requirements. As stated above, the Commission agrees with the staff's longstanding interpretation that special packaging requirements extend to applicators intended to replace primary closures when used and stored in the home.

B. Toxicity of Minoxidil

The Commission's Directorate for Epidemiology and Health Sciences reviewed the toxicity of minoxidil. This includes both information concerning the therapeutic ingestion of prescription minoxidil tablets to treat hypertension and ingestion of topical

minoxidil. In either form, when it is ingested, minoxidil is rapidly and almost completely (over 95 percent) absorbed by the gastrointestinal tract and is distributed systematically throughout the body. In contrast, minoxidil is very poorly absorbed through the skin, and insufficient levels of minoxidil reach the bloodstream to cause effects on vascular and cardiac function. This is why a topical solution of two percent minoxidil is considered safe when used on the skin as directed but can be harmful if ingested.(2)

The tablet form of minoxidil is prescribed for use as an antihypertensive drug. It lowers blood pressure by relaxing the smooth muscle of the arteries. The body's nervous system responds by causing the heart to beat faster (tachycardia and with more force (increased cardiac output) to compensate for the drop in blood pressure. Minoxidil tablets are typically used in combination with a β -adrenergic blocking agent and a diuretic to maximize its effect on blood pressure while minimizing associated side effects (the cardiac response and retention of fluids).(2)

The most prominent effects from therapeutic ingestion of minoxidil are increased heart rate, increased cardiac output and decreased blood pressure. When blood pressure becomes abnormally low (hypotension), it can lead to lethargy and lightheadedness with the possibility of damage to the heart and other tissues with high oxygen demand, if left untreated. Less frequent effects include salt and fluid retention and edema, aggravation of angina, and pericardial effusion (massive fluid accumulation

around the heart) in patients with renal impairment. Repeated ingestion over several months can produce hypertrichosis (overstimulated hair growth) particularly to the face and to a lesser extent to the limbs and scalp. Less severe symptoms of nausea, headache, fatigue, and dermatologic reactions have been occasionally reported.(2)

Prescription minoxidil is available as 2.5 mg, 5 mg, and 10 mg tablets. The effective dosage is usually between 0.2 to 1 mg/kg/day (roughly 5 to 40 mg/day for an adult) depending on the individual and the desired antihypertensive response. Use in children has been limited with a similar effective body weight-normalized dose range as adults (0.2 to 1 mg/kg/day). Because of possible adverse effects, the maximum recommended daily therapeutic dosage is 100 mg in adults and 50 mg for children under the age of 12.(2)

C. Incident Data

The staff reviewed several sources for information of adverse health effects from ingestions of minoxidil. These sources are the American Association of Poison Control Centers ("AAPCC"), the FDA Spontaneous Reporting System ("SRS"), published reports in the medical literature, and reports from the injury surveillance databases maintained by the Commission. The most commonly cited injuries are prolonged hypotension and tachycardia that require hospitalization. There were reports of two deaths associated with minoxidil overdose.

AAPCC Data. The AAPCC collects reports made to participating poison control centers throughout the United States. A retrospective study evaluated AAPCC records of all minoxidil exposures from 1985 through 1991. (The study did not distinguish between ingestions of minoxidil tablets and topical solution.) During this time period, 285 incidents were reported. About half (51 percent) of these occurred in children under six years of age. Most of the 285 incidents were reportedly accidental ingestions (80%) and some involved co-ingestions (21%) of other substances. The most frequently reported adverse effects from 16 incidents involving moderate to severe poisoning were hypotension (69%), tachycardia (38%), and lethargy (31%) with 44% requiring medical treatment. Most of the more serious poisonings were intentional ingestions (69%) and involved co-ingestions (81%). It was not reported how many of these incidents occurred in children. There was one reported death caused by an intentional ingestion of minoxidil with other vasodilators, and acetaminophen.(2)

CPSC obtains annual AAPCC data on pediatric exposures to children under six years of age. Four accidental ingestions of topical minoxidil liquid were reported in 1995. (Prior to 1995, topical minoxidil was not given a specific code within the AAPCC database.) None of these four incidents led to serious toxicity. In 1996, the number of reported cases increased to 43. One of these exhibited moderate effects.

Because incidents involving minoxidil tablets (rather than topical solutions) are coded in a category that includes "other vasodilators," it is not possible to isolate incidents specific to minoxidil tablets. There were two childhood ingestions of "other vasodilators" reported in 1995 that resulted in a moderate toxicity.(2)

FDA/SRS Database

The SRS is a database maintained by the FDA for reports of adverse reactions detected after a drug goes on the market. Drug manufacturers are required to report any known incidents of adverse effects associated with their products. However, the incident reports are not verified by the FDA, and therefore, the adverse effects may reflect underlying diseases or reactions to multiple drugs.

There have been 16,795 SRS reports on topical minoxidil between 1983 and March 1997. Most of the reported adverse effects were dermal reactions to excessive application of topical minoxidil to the scalp. However, FDA specifically cited five overdose ingestion cases involving topical minoxidil. Three of these led to serious outcomes.(2)

One of these cases was a suicide in which an adult male ingested the contents of five bottles (6 grams in 300 ml) of topical minoxidil and died. No other details were provided. A second case was an adult male who mistakenly ingested 15-20 ml (300 - 400 mg) of topical minoxidil and experienced fainting, severe hypotension, cardiac effects, and acute renal failure.

The person was taking anti-hypertensive medication at the time of the poisoning but no other details of his prior medical condition were cited. The third case was an ingestion of topical minoxidil by a two-year-old child. She was found with an empty bottle that had been full earlier. She was admitted to an intensive care unit in a lethargic state with a pulse of 160 (above normal range) , blood pressure of 106/60 (within normal limits), but was discharged the same day. The amount of minoxidil actually ingested was never established.(2)

In addition, two possible childhood ingestions of topical minoxidil were reported in SRS to result in hospital visits. In both incidents, no adverse outcomes were recorded but the children were retained at the hospital for observation. While the children gained access to the medication in these cases, the hospital suspected that no minoxidil was consumed.(2)

CPSC Databases

CPSC has several databases for poison incidents. The staff reviewed cases from 1988 to 1997 in the National Electronic Injury Surveillance System ("NEISS"). NEISS monitors emergency room visits to a statistically-based sample of selected hospitals throughout the United States. One childhood poisoning case associated with minoxidil was reported in the NEISS database during that time period. This was an ingestion of an unknown quantity of topical minoxidil by a two-year-old male. The child was seen in an emergency room with normal temperature, pulse, and respiration and was released the same day without treatment.

It is not known whether the minoxidil package was secured with a child-resistant closure at the time of the incident.(2)

The staff also reviewed CPSC's Injury and Potential Injury Incident ("IPII") files of consumer product-related incidents reported through letters, telephone calls, media articles and Death Certificate files of consumer product-related deaths. There were no minoxidil-related injuries or deaths found in these databases for the 1988 to 1997 time period.(2)

Medical Literature

Five case reports of injuries following minoxidil ingestion were found in the published literature. Two cases involved young children. In one instance, a two-year-old ingested an unconfirmed number of minoxidil tablets. In the second instance, a three-year-old swallowed an estimated 1-2 milliliters of three percent minoxidil solution (30-60 milligrams). Both children were seen at hospitals experiencing moderate tachycardia but no other reported abnormalities. The three other reports were intentional ingestions by adults of minoxidil tablets (one case) or two percent liquid (two cases). The latter two cases involved consumption of several hundred milligrams of minoxidil (10-20 mg/kg) along with alcohol and, in one case, several other substances. The clinical courses were similar. A few hours after ingestion, each individual was admitted to a hospital, usually in a disoriented and unresponsive state. They became moderately to severely hypotensive with tachycardia and elevated cardiac output. Medical treatment was administered and the

patient's cardiac and vascular signs eventually normalized over the next 36 to 72 hours. In each instance, it was concluded that minoxidil was primarily responsible for the observed effects, and that co-ingested substances were not consumed in amounts sufficient to cause the reported symptoms.(2)

D. Level for Regulation

The Commission is proposing a rule that would require special packaging for minoxidil products containing more than 14 mg of minoxidil in a single package. This is based on the maximum recommended therapeutic dose of minoxidil for an adult. The 14 mg dose level corresponds to 1.4 mg/kg for a 10 kg child. The equivalent minoxidil dose for the average 70 kg adult would be approximately 100 mg. The regulated dose level is expected to reasonably protect children under five years of age from serious personal injury or illness.(2)

E. Statutory Considerations

1. Hazard to Children

As noted above, the toxicity data concerning ingestion of minoxidil demonstrate that minoxidil can cause serious illness and injury to children. Moreover, it is available to children in OTC topical minoxidil preparations. Although as far as the Commission is aware, all primary product containers for topical minoxidil products currently use CR packaging, all applicators are not CR. Some packages contain applicators meant to be used as closures after first use which are not CR. The Commission preliminarily concludes that a regulation is needed to ensure

that products subject to the regulation, including applicators intended to be used as closures, will be placed in CR packaging by any current as well as new manufacturers.

Pursuant to section 3(a) of the PPPA, 15 U.S.C. 1472(a), the Commission preliminarily finds that the degree and nature of the hazard to children from handling or ingesting minoxidil is such that special packaging is required to protect children from serious illness. The Commission bases this finding on the toxic nature of minoxidil products and their accessibility to children in the home.

2. Technical Feasibility, Practicability, and Appropriateness

In issuing a standard for special packaging under the PPPA, the Commission is required to find that the special packaging is "technically feasible, practicable., and appropriate." 15 U.S.C. 1472(a)(2). Technical feasibility may be found when technology exists or can be readily developed and implemented by the effective date to produce packaging that conforms to the standards. Practicability means that special packaging complying with the standards can utilize modern mass production and assembly line techniques. Packaging is appropriate when complying packaging will adequately protect the integrity of the substance and not interfere with its intended storage or use.

a. Primary Product Containers

The primary product containers for all topical minoxidil products that the Commission is aware of have continuous threaded reclosable packaging. All of these closures that the staff

examined were CR and SF. Thus, it is clear that CR packaging for primary product containers is technically feasible, practicable and appropriate. (4)

b. Applicators

As discussed above, topical minoxidil packages contain applicators -- droppers and/or metered finger mechanical sprayers -- intended to replace the original closures. Eight products have droppers that are CR and SF. This indicates that such droppers are technically feasible, practicable and appropriate. (4)

The Commission knows of eight minoxidil products that include a non-CR finger sprayer. Child-resistance for a finger sprayer means that it must be significantly difficult for children to (1) remove the finger sprayer closure from the container and (2) activate the finger sprayer mechanism to obtain an amount above the regulated level. One packaging manufacturer has developed a prototype CR metered finger sprayer applicator which the manufacturer believes can be modified to pass senior adult effectiveness testing in approximately 12 months. Additional time may be required to provide commercial quantities of this type of packaging. As discussed above, an applicator that cannot be used as a closure does not need to be CR. (4)

Three products for women also contain an extender to be used with the finger sprayer. Under the proposed rule, when the extender is attached to the finger sprayer, this applicator mechanism must be CR. That is, it must be significantly

difficult for children to (1) remove the combined finger sprayer and extender from the container and (2) activate the combined finger sprayer and extender to obtain an amount above the regulated level. Currently no finger sprayers with extenders are CR. As noted above, CR/SF finger sprayer could be developed within 12 months. Some modifications to the extender may be needed so that it would operate with the CR finger sprayer.@)

3. Other Considerations

In establishing a special packaging standard under the PPPA, the Commission must consider the following:

- a. The reasonableness of the standard;
- b. Available scientific, medical, and engineering data concerning special packaging and concerning childhood accidental ingestions, illness, and injury caused by household substances;
- c. The manufacturing practices of industries affected by the PPPA; and
- d. The nature and use of the household substance. 15 U.S.C. 1472 (b).

The Commission has considered these factors with respect to the various determinations made in this notice, and preliminarily finds no reason to conclude that the rule is unreasonable or otherwise inappropriate.

F. Effective Date

The PPPA provides that no regulation shall take effect sooner than 180 days or later than one year from the date such final regulation is **issued**, except that, for good cause, the

Commission may establish an earlier effective date if it determines an earlier date to be in the public interest. 15 U.S.C. 1471n.

Senior-friendly special packaging is currently commercially available for most types of CR packaging. Primary product containers for topical minoxidil are already CR and SF. Most droppers intended to replace the original closures are also CR **and** SF. One packaging manufacturer has developed a prototype CR finger sprayer that the manufacturer believes can be modified to pass senior adult effectiveness testing in approximately 12 months. Additional time may be required to provide commercial quantities of this type of packaging. Modifications to the extender would likely require a similar amount of time. Thus, the Commission proposes that a final rule would take effect (1) six months after publication of the final rule for primary closures and dropper applicators and (2) 12 months after publication of the final rule for metered finger sprayer applicators and extenders,, The Commission also proposes that if additional time is necessary to produce commercial quantities, manufacturers could request a temporary stay of enforcement for the finger sprayer and extender. A final rule would apply to products that are packaged on or after the effective date.

G. Regulatory Flexibility Act Certification

When an agency undertakes a rulemaking proceeding, the Regulatory Flexibility Act, 5 U.S.C. 601 et seq., generally requires the agency to prepare proposed and final regulatory

flexibility analyses describing the impact of the rule on small businesses and other small entities. Section 605 of the Act provides that an agency is not required to prepare a regulatory flexibility analysis if the head of an agency certifies that the rule will not have a significant economic impact on a substantial number of small entities.

The Commission's Directorate for Economic Analysis prepared a preliminary assessment of the impact of a rule to require special packaging topical minoxidil products containing more than 14 mg of minoxidil in a single package.

This assessment reports that the staff is aware of 16 marketers of minoxidil-containing products. Ten of these are manufacturers, and two of the ten are small companies.(3)

As mentioned above, at the present time, the primary packaging for all topical minoxidil products is CR. Thus, there will be no additional cost to existing firms to use CR primary packaging. Firms entering the market in the future will find readily available CR primary packaging at prices competitive with non-CR packaging.(3)

Similarly, companies now using CR dropper applicators intended to be used as closures will not incur any additional cost. For other companies to switch from non-CR droppers, there is an estimated 5 cent incremental cost of a CR dropper compared with a non-CR dropper. This cost is small relative to the retail price of a minoxidil product (\$6-\$30).(3)

Because there are no CR metered finger mechanical sprayer applicators or extenders currently on the market, the staff has no information on the incremental cost of senior friendly cr finger sprayers and **extenders.**(3) Firms do have the option of supplying only a CR/SF dropper applicator. They also could supply any type of applicator that is not intended to be used as a closure.

Based on this assessment, the Commission preliminarily concludes that the proposed requirement for minoxidil products would not have'a significant impact on a substantial number of small businesses or other small entities. The Commission seeks additional information on the possible impact on small business.

H. Environmental Considerations

Pursuant to the National Environmental Policy Act, and in accordance with the Council on Environmental Quality regulations and CPSC procedures for environmental review, the Commission has assessed the possible environmental effects associated with the proposed PPPA requirements for minoxidil-containing products.

The Commission's regulations state that rules requiring special packaging for consumer products normally have little or no potential for affecting the human environment. 16 CFR 1021.5(c) (3). Nothing in this proposed rule alters that **expectation.**(3) Therefore, because the rule would have no adverse effect on the environment, neither an environmental assessment nor an environmental impact statement is required.

I. Executive Orders

According to Executive Order 12988 (February 5, 1996), agencies must state in clear language the preemptive effect, if any, of new regulations.

The PPPA provides that, generally, when a special packaging standard issued under the PPPA is in effect, "no State or political subdivision thereof shall have any authority either to establish or continue in effect, with respect to such household substance, any standard for special packaging (and any exemption therefrom and requirement related thereto) which is not identical to the [PPPA] standard." 15 U.S.C. 1476(a). A State or local standard may be excepted from this preemptive effect if (1) the State or local standard provides a higher degree of protection from the risk of injury or illness than the PPPA standard; and (2) the State or political subdivision applies to the Commission for an exemption from the PPPA's preemption clause and the Commission grants the exemption through a process specified at 16 CFR Part 1061. 15 U.S.C. 1476(c) (1). In addition, the Federal government, or a State or local government, may establish and continue in effect a non-identical special packaging requirement that provides a higher degree of protection than the PPPA requirement for a household substance for the Federal, State or local government's own use. 15 U.S.C. 1476(b).

Thus, with the exceptions noted above, the proposed rule requiring CR packaging for products containing more than 14 mg

minoxidil would preempt non-identical state or local special packaging standards for such minoxidil containing products.

In accordance with Executive Order **12612** (October 26, 1987), the Commission certifies that the proposed rule does not have sufficient implications for federalism to warrant a Federalism Assessment.

List of Subjects in 16 CFR Part 1700

Consumer protection, Drugs, Infants and children, Packaging and containers, Poison prevention, Toxic substances.

For the reasons given above, the Commission proposes to amend 16 CFR part 1700 as follows:

PART 1700-- [AMENDED]

1. The authority citation for part 1700 continues to read as follows:

Authority: Pub. L. 91-601, secs. 1-9, 84 Stat. 1670-74, 15 U.S.C. **1471-76**. Secs 1700.1 and 1700.14 also issued under Pub. L. 92-573, sec. 30(a), 88 Stat. **1231**. **15** U.S.C. 2079(a).

2. Section 1700.14 is amended by adding new paragraph **(a) (28)** to read as follows (although unchanged, the introductory text of paragraphs (a) and **(10)** are included below for context):

§ 1700.14 Substances requiring special packaging.

(a) **Subs tances.** The Commission has determined that the degree or nature of the hazard to children in the availability of the following substances, by reason of their packaging, is such that special packaging meeting the requirements of § 1700.20(a) is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substances, and the special packaging herein required is technically feasible, practicable, and appropriate for these substances:

* * * * *

(28) *Minoxidil*. Minoxidil preparations for human use and containing more than 14 mg of minoxidil in a single retail package shall be packaged in accordance with the provisions of § 1700.15(a), (b) and (c). Any applicator packaged with the minoxidil preparation and intended to replace the original closure shall also comply with the provisions of § 1700.15(a), (b) and (c).

Dated: _____

Sadye E. Dunn,
Secretary, Consumer Product Safety Commission

List of Relevant Documents

1. Briefing memorandum from Val Schaeffer, Ph.D., EH, to the Commission, "Proposed Rule to Require Child-Resistant Packaging for Topical Minoxidil," February ___, 1998.

2. Memorandum from Val Schaeffer, Ph.D., EH, to Marilyn Wind, Ph.D., Director, Health Sciences Division, "Toxicity Assessment of Topical Minoxidil" November 14, 1997.

3. Memorandum from Marcia P. Robins, EC, to Val Schaeffer, Ph.D., EH, "Economic Considerations of a Proposal to Require Child-Resistant Packaging for Drug Preparations Containing Minoxidil," January 5, 1998.

4. Memorandum from Charles Wilbur, EH, to Val Schaeffer, Ph.D., EH, "Technical Feasibility, Practicability, and Appropriateness Determination for the Proposed Rule to Require Special Packaging for Products Containing Minoxidil," December 16, 1997.

5. Memorandum from Michael T. Bogumill, CRM, to Val Schaeffer, Ph.D., EH, "Special Packaging of Oral Prescription Drugs in Dropper Bottles," December 17, 1997.